

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CELLECTIS S.A.,)	
)	
Plaintiff,)	
)	
v.)	Civ. No. 11-173-SLR
)	
PRECISION BIOSCIENCES,)	
)	
Defendant.)	

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MEMORANDUM OPINION

Dated: August 6, 2012
Wilmington, Delaware


ROBINSON, District Judge

I. INTRODUCTION

Plaintiff Collectis S.A. (“Collectis”) filed the present action against defendant Precision Biosciences, Inc. (“Precision”) on March 1, 2011, alleging infringement of U.S. Patent No. 7,897,372 (“the ‘372 patent”), which is assigned to Collectis. (D.I. 1) The ‘372 patent, entitled “I-CreI Meganuclease Variants with Modified Specificity, Method of Preparation and Uses Thereof,” is directed to particular I-CreI meganucleases having mutations that permit binding and cleavage of DNA at specific sites. (*Id.* at ¶ 8) Currently before the court is Precision’s motion to stay the present litigation pending the completion of *ex parte* reexamination of the ‘372 patent. (D.I. 41) Also before the court is Precision’s motion for leave to amend its answer and counterclaims to add allegations of inequitable conduct in the procurement of the ‘372 patent. (D.I. 113) For the reasons that follow, the court denies both motions.

II. BACKGROUND

A. Procedural Posture

The litigation history between Collectis and Precision is extensive. In March of 2008, Collectis sued Precision in the United States District Court for the Eastern District of North Carolina for infringement of U.S. Patent Nos. 6,610,545 (“the ‘545 patent”) and 7,309,605 (“the ‘605 patent”). *See Collectis S.A. v. Precision BioSciences, Inc.*, Civ. No. 08-118 (E.D.N.C.) (“*North Carolina I*”). The ‘545 and ‘605 patents each issued from an application first filed by Institut Pasteur in 1992, and relate to DNA encoding the meganuclease I-SceI. Subsequent to the initiation of suit, Precision requested, and was granted, *inter partes* reexamination of the ‘545 and ‘605 patents. Precision filed a

motion to stay *North Carolina I*, which motion was granted in August 2010 at the close of fact discovery. (D.I. 23 at 6) The United States Patent and Trademark Office ("PTO") has since rejected the claims of the '545 and '605 patents, and the Board of Patent Appeals and Interferences affirmed the rejection.¹

On March 1, 2011 at 5:59 a.m., as soon as U.S. Patent No. 7,897,372 ("the '372 patent") issued and was publicly available from the PTO's website, Collectis filed the instant litigation against Precision for infringement of the '372 patent.² Later that same day, Precision filed a declaratory judgment action on the '372 patent in North Carolina (E.D.N.C. Civ. No. 11-91 ("*North Carolina II*")).

On March 22, 2011, Collectis filed a motion to enjoin Precision from prosecuting its declaratory judgment actions. (D.I. 7)³ Thereafter, Precision answered the complaint in this action and asserted affirmative defenses and counterclaims of noninfringement and invalidity of the '372 patent. (D.I. 10) On April 8, 2011, Precision filed a motion to transfer the present action to the United States District Court for the Eastern District of North Carolina. (D.I. 16)

On April 18, 2011, Collectis amended its complaint in this action and added

¹It is not clear whether Collectis has appealed to the Federal Circuit. (E.D.N.C. Civ. No. 08-119, D.I. 213)

²Previously, on November 30, 2010, Collectis filed an action for infringement of U.S. Patent No. 7,842,489 ("the '489 patent") against Precision in this court. (Civ. No. 10-1033-SLR) On December 6, 2010, Precision filed a declaratory judgment action in the Eastern District of North Carolina regarding the '489 patent. The parties have since resolved both cases by stipulation filed on October 28, 2011. (Civ. No. 10-1033, D.I. 57)

³Docket item numbers will hereinafter reference the present suit, unless otherwise specifically noted.

claims of unfair competition (“count II”) and violations of the Lanham Act, 15 U.S.C. § 1125(a) (“count III”), each relating to allegedly false and misleading commercial representations on Precision’s website. (D.I. 22 at ¶¶ 15-19, 24-31) Precision filed a Request for *Ex Parte* Reexamination of the ‘372 patent with the PTO on April 29, 2011. (D.I. 42 at 6) Precision filed its answer to Collectis’s amended complaint on May 5, 2011, adding a third affirmative defense that Collectis is barred from relief on counts II and III of its amended complaint “in whole or in part by laches, estoppel and/or other equitable doctrines.” (D.I. 27 at 5) The court entered a scheduling order on May 17, 2011. (D.I. 33)

The PTO granted Precision’s request for *ex parte* reexamination of the ‘372 patent on July 8, 2011 and, on August 8, 2011, Precision filed a motion to stay the present suit pending the outcome of that proceeding. (D.I. 41; D.I. 42 at 1, 6) On December 6, 2011, Collectis filed a request for a certificate of correction for the ‘372 patent to change its claim of priority under 35 U.S.C. § 119 to a claim of priority under 35 U.S.C. § 120. (D.I. 113, ex. A at ¶ 31) The PTO issued the certificate on January 10, 2012.

Discovery has since proceeded in the litigation. On March 28, 2012, Precision moved for leave to amend its answer to add claims of inequitable conduct in the procurement of the ‘372 patent. (D.I. 113) On May 3, 2012, upon consideration of all of the relevant factors, the court found that Precision did not tip the scales in favor of transferring the case to North Carolina, and denied Precision’s motion to transfer. (D.I. 134; D.I. 135) The court also found that the instant suit (Civ. No. 11-173) was the first-filed case vis a vis *North Carolina II*. Insofar as none of the exceptions to the first-filed

rule were applicable, the court granted Collectis' motion to enjoin the North Carolina litigation. (*Id.*)

B. The '372 Patent

The '372 patent, entitled "I-Crel Meganuclease Variants with Modified Specificity, Method of Preparation and Uses Thereof," is directed to particular mutated I-Crel meganucleases that bind and cleave DNA at specific sites. The '372 patent issued from U.S. Patent Application Serial No. 11/908,798 ("the '798 application"), the U.S. phase application under 35 U.S.C. § 271 of PCT No. PCT/IB2006/001203, filed March 15, 2006 (hereinafter, the "Parent PCT"). The Parent PCT, in turn, claimed priority to two foreign applications: (1) PCT/IB2005/000981 (March 15, 2005); and (2) PCT/IB2005/003083 (September 19, 2005). The '372 patent names two inventors: Philippe Duchateau ("Duchateau"); and Frederic Paques ("Paques").

C. Reexamination Status

The PTO mailed its initial Office Action rejecting all claims (1-54) of the '372 patent on January 18, 2012. Therein, the examiner rejected claims 1-10, 13-16, 19-28, 31-34, 37-46 and 49-52 as anticipated under 35 U.S.C. § 102(e) by another Collectis patent application, WO 2004/067736 by Arnould et al. ("Arnould"). (D.I. 70) Arnould is a PCT (international) application bearing a filing date of January 28, 2004; priority is claimed to two United States publications published January 28, 2003 and August 1, 2003.⁴ (D.I. 113, ex. 1) Arnould lists several inventors: (1) Duchateau; (2) Paques; (3)

⁴January 28, 2003 is more than a year before the earliest claimed priority date of the '372 patent; Arnould's publication date (August 12, 2004) is less than a year from the filing date of the '798 application that issued as the '372 patent.

Sylvain Arnould (“S. Arnould”); (4) Jean-Pierre Cabaniols; (5) Patrick Chames (“Chames”); (6) Andre Chouluka; Jean-Charles Epinat (“J.C. Epinat”); (7) Emmanuel LaCroix (“LaCroix”); (8) Christophe Perez-Michaut; (9) Julianne Smith; and (10) David Sourdive. (*Id.*)

The examiner asserts that Arnould discloses SEQ ID 70 as claimed in independent claim 1, as Arnould’s SEQ ID 5 (Fig. 2C) encodes the first 164 residues of this sequence. (D.I. 116, ex. 9 at p.4) Further, the examiner has rejected the claims under 35 U.S.C. § 103(a) as obvious on several grounds, as follows: (1) claims 1-4, 6-22, 24-40 and 42-53 are obvious in view of Arnould in view of an article in Nucleic Acids Reserch by Epinat et al.,⁵ and (2) claims 1-4, 6-22-24-40 and 42-54 are obvious in view of an article by Chevalier et al. and other references.⁶ (*Id.* at p.6-9)

In response to the PTO’s first office action in the reexamination of the ‘372 patent, Collectis has petitioned the PTO to change inventorship on the ‘372 patent by adding S. Arnould, Chames, Epinat and LaCroix as inventors, thereby creating unity of inventorship between the ‘372 patent and Arnould. (D.I. 140 at p.12) More specifically, Collectis has provided a declaration stating that the subject matter of Arnould cited by the examiner originated from these six inventors. (*Id.* at p.13) Collectis has also asked the examiner to confirm that the ‘372 patent has the benefit of priority to PCT/IB2005/000981 – the earlier of the two foreign applications to which the Parent

⁵Epinat et al., 31(11) Nucleic Acids Res. 2952-2962 (2003).

⁶Chevalier et al., 329 J. Mol. Biol. 253-69 (2003); Seligman, D. et al., *Mutations Altering the Cleavage Specificity of a Homing Endonuclease*, 30(17) Nucleic Acids Research 3870-79 (2002); Chevalier et al., *Design, Activity and Structure of a Highly Specific Artificial Endonuclease*, 10 Molecular Cell 895-905 (2002). (D.I. 70 at p.3)

PCT claims priority with a priority date of March 15, 2005. (*Id.*)

D. Facts Relevant to Precision's Motion to Amend

Arnould is not only the subject of the currently-pending reexamination of the '372 patent, but was at issue during prosecution of the '798 application leading to the '372 patent. Precision avers that on May 20, 2010, before the PTO had issued a decision on the merits of the '798 application, Paques and prosecuting attorney Dr. Vincent Shier ("Shier") attended an in-person interview with the examiner. (D.I. 113, ex. A at ¶ 21) The record of the interview indicates that Arnould was discussed, specifically, the examiner sought an explanation of the differences between Arnould and the '798 application. (*Id.*) Collectis, through Shier, responded to this inquiry by preliminary amendment (dated July 26, 2010), stating as follows:

[T]he claimed invention differs from [Arnould] in that this reference at best provides for a library of mutant meganucleases where residues 44, 68 and 70 are altered. However, in the present invention, it is required that the monomer further comprises at least one additional mutation of an amino acid residue directly contacting a DNA target at other positions (see claims 59 and 95) and further defines that the at least one additional mutation of an amino acid sequence directly contacting a DNA target sequence is selected from the group consisting of positions 26, 28, 30, 32, 33 and 38 (see claims 60 and 96). This concept and the variant meganucleases are not disclosed in [Arnould] and, as such, would not affect the patentability of the claimed invention.

(*Id.* at ¶ 22; D.I. 113, ex. 2 at 20-21)

Precision claims that these statements were known to be "unequivocally false" by Shier and Paques when they were made, and cites the purportedly missing specific disclosures within Arnould. (D.I. 113, ex. A at ¶¶ 23-24) For example, Arnould discloses an intermediate library: "Lib1 (residues 26, 28, 30, 33 and 38 mutated[.])." (*Id.* at ¶ 24) Precision avers that, "[b]ut for these false statements, the PTO would not have

granted the claims of the '372 patent because the disclosure of [Arnould] includes all elements of [the] claims of the '372 patent or would, at a minimum, render those claims obvious.” (*Id.* at ¶ 26)

With respect to intent to deceive, Precision states generally that “Dr. Shier and Dr. Paques knew these statements were unequivocally false since they were characterizing Collectis and Dr. Paques’ own work and patent application, and since Dr. Shier himself prosecuted the United States counterpart to [Arnould] in which prosecution he made diametrically opposite representations to the PTO.” (*Id.* at ¶ 23; see also *id.* at ¶ 28) Specifically, Precision alleges that, six months prior to the preliminary amendment dated July 26, 2010, Shier and Paques told the PTO that Arnould teaches methods of making I-Crel variant meganucleases with substitutions at positions 26, 28, 30, 33, 38, 44, 68 and 70.⁷ (*Id.* at ¶ 29)

As noted above, Collectis sought and obtained the request for a certificate of correction for the '372 patent to change its claim of priority under 35 U.S.C. § 119 to a claim of priority under 35 U.S.C. § 120. Precision avers that “Collectis and [Shier’s] action in seeking the certificate of correction further evidences their knowledge that the [Arnould] reference discloses the claimed invention of the '372 patent claims and that [Shier and Paques’] earlier representations to the PTO regarding the scope and content of [Arnould] on behalf of Collectis were false.” (*Id.*)

⁷The court does not have before it the December 14, 2009 amendment to the United States counterpart to Arnould referenced by Precision.

III. STANDARDS

A. Motion to Stay

Motions to stay invoke the broad discretionary powers of the court. *Dentsply Int'l, Inc. v. Kerr Mfg. Co.*, 734 F.Supp. 656, 658 (D. Del. 1990) (citing *Bechtel Corp. v. Laborers' Int'l Union*, 544 F.2d 1207, 1215 (3d Cir. 1976)). Three general factors inform the court in this regard:

(1) whether the granting of a stay would cause the non-moving party to suffer undue prejudice from any delay or allow the moving party to gain a clear tactical advantage over the non-moving party; (2) whether a stay will simplify the issues for trial; and (3) whether discovery is complete and a trial date set.

Enhanced Security Research, LLC v. Cisco Sys., Inc., Civ. No. 09–571, 2010 WL 2573925, at *3 (D. Del. June 25, 2010) (citing *St. Clair Intellectual Prop. Consultants v. Sony Corp.*, Civ. No. 01–557, 2003 WL 25283239, at *1 (D. Del. Jan. 30, 2003)).

B. Motion to Amend

“[L]eave to amend ‘shall be freely given when justice so requires.’” *Foman v. Davis*, 371 U.S. 178, 182 (1962) (quoting Fed. R. Civ. P. 15(a)). The court may exercise its discretion to deny leave to amend in situations in which the moving party has delayed seeking leave and the delay “is undue, motivated by bad faith, or prejudicial to the opposing party.” *Bjorgung v. Whitetail Resort, LP*, 550 F.3d 263, 266 (3d Cir. 2008) (citation omitted). Put another way, where the non-moving party will not suffer “substantial or undue prejudice,” “denial [of leave to amend] must be based on bad faith or dilatory motives, truly undue or unexplained delay, repeated failures to cure the deficiency by amendments previously allowed, or futility of amendment.” *USX Corp. v. Barnhart*, 395 F.3d 161, 166 (3d Cir. 2004) (quoting *Lorenz v. CSX Corp.*, 1 F.3d

1406, 1413-14 (3d Cir. 1993)). Delay is “undue” when an unwarranted burden is placed on the court or when the requesting party has had previous opportunities to amend. *See Estate of Oliva ex rel. McHugh v. New Jersey*, 604 F.3d 788, 803 (3d Cir. 2010) (citation omitted).

IV. DISCUSSION

A. Precision’s Motion to Stay

This court has previously articulated factors which bear upon whether “there is ‘even a fair possibility’ that the stay would work damage on another party” in weighing the propriety of staying litigation in favor of *inter partes* reexamination proceedings. *See Belden Techs. Inc. v. Superior Essex Comm’s LP*, Civ. No. 08–63, 2010 WL 3522327 (Sept. 2, 2010) (citing *Dentsply Int’l*, 734 F.Supp. at 658 (internal citations omitted)). In passing the America Invents Act, Congress has negated the need for the court’s balancing of such factors. The court is now mandated to stay litigation in favor of *inter partes* reexamination “unless the court before which such litigation is pending determines that a stay would not serve the interests of justice.”⁸ 35 U.S.C. § 318.

No comparable stay provision was included in the AIA with respect to *ex parte* reexaminations, which are granted by the PTO if a “substantial new question of patentability” is presented. That is, there is no indication inherent to the granting of an *ex parte* reexamination that continued prosecution will likely result in the changing of

⁸Congress mandated that the PTO may now only grant *inter partes* reexamination/review proceedings after September 16, 2011 if it believes there is a “reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” Leahy–Smith America Invents Act, Pub. L. No. 112–29, § 314(a), 125 Stat 284 (Sept. 16, 2011). A stay of litigation is practical given the PTO’s determination that the claims under reexamination will likely change.

claims.

While the court's framework articulated in *Belden, supra*, and its progeny remain applicable in this context, the Federal Circuit's recent jurisprudence is also informative. In *In re Baxter International, Inc.*, — F.3d —, 2012 WL 1758093 (Fed. Cir. May 17, 2012) (hereinafter, "*Baxter*"), litigation on the patent at issue (U.S. Patent No. 5,247,434, or "the '434 patent") had concluded in the United States District Court for the Northern District of California with that court reversing the jury's verdict that the '434 patent claims were invalid. *Id.* at *2. Meanwhile, concurrent reexamination proceedings concluded with the examiner's rejection of several claims of the '434 patent as obvious in view of the prior art. *Id.* The Federal Circuit thereafter affirmed the district court's grant of judgment as a matter of law, albeit for different reasons than those articulated by the trial court. *Id.* The Board of Patent Appeals and Interferences ("BPAI") was directed to consider the Federal Circuit's decision, but subsequently affirmed the examiner's rejections citing the "lower standard of proof and the broadest reasonable interpretation standard of claim construction [that] apply at the PTO[.]" *Id.* at *3.

On appeal (now for the second time), the Federal Circuit affirmed the rejection of the '434 patent claims by the BPAI on the basis that substantial evidence supported the BPAI's findings regarding the disclosures of the prior art. *Id.* at *6. In so doing, the Court emphasized that the PTO and district courts "take different approaches in determining validity and on the same evidence could quite correctly come to different conclusions," i.e., "the two proceedings necessarily applied different burdens of proof

and relied on different records.”⁹ *Id.* at *6-7. Judge Newman dissented, arguing that the PTO has no authority to nullify a final judicial determination, i.e., to ignore “the law of the case.” *Id.* at *8-13.

Baxter demonstrates that, while unification of result between concurrent PTO and judicial proceedings is desirable,¹⁰ it is neither the standard nor a practical reality given that the Federal Circuit may reach different and, in fact, inconsistent results in the subsequent appeals. That Court has made clear that “elevat[ing] a decision by the PTO over a decision by a federal district court” would be “erroneous[],” *id.* at *7; therefore, the court need not defer to the PTO’s expertise in evaluating the claims at issue.

The court has previously “observe[d] that the strategy of responding to litigation by pursuing reexamination is simply another example of forum-shopping, perfectly legitimate but, nonetheless, a way to postpone a patent holder’s day in court.” *Collectis S.A. v. Precision Biosciences, Inc.*, — F. Supp. 2d —, 2012 WL 1556489 at *7 (D. Del. May 3, 2012). As detailed above, the litigation history demonstrates that the parties at bar have each maneuvered for their preferred forums. While Precision filed its reexamination request promptly, Collectis initiated the present suit on the day of the ‘372 patent’s issuance. *Cf. Belden*, 2010 WL 3522327 at *2 (“A request for

⁹The Federal Circuit noted that “the patent examiner relied on new prior art that had not been raised in the prior district court proceeding. Why Fresenius did not present that prior art before the district court we do not know.” *Baxter*, 2012 WL 1758093 at *7.

¹⁰“When a party who has lost in a court proceeding challenging a patent, from which no additional appeal is possible, provokes a reexamination in the PTO, using the same presentations and arguments, even with a more lenient standard of proof, the PTO ideally should not arrive at a different conclusion.” *Baxter*, 2012 WL 1758093 at *7.

reexamination made **well after** the onset of litigation followed by a subsequent request to stay may lead to an inference that the moving party is seeking an inappropriate tactical advantage.”) (emphasis added). Furthermore, discovery in this case is nearing completion¹¹ and the concurrent reexamination is still in its infancy.¹² In sum, the court declines to stay the instant case in its discretion in view of *Baxter* and in further view of the *Belden* factors articulated herein.

B. Precision’s Motion to Amend

Futility of amendment occurs when the complaint, as amended, does not state a claim upon which relief can be granted. See *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997). If the proposed amendment “is frivolous or advances a claim or defense that is legally insufficient on its face, the court may deny leave to amend.” *Harrison Beverage Co. v. Dribeck Importers, Inc.*, 133 F.R.D. 463, 468 (D.N.J. 1990).

To prove inequitable conduct, Precision must demonstrate that reexamination counsel had the specific intent to mislead the PTO; intent cannot be solely inferred from materiality. See *Therasense*, 2011 WL 2028255 at *10. “[T]o meet the clear and convincing evidence standard, the specific intent to deceive must be the single most

¹¹The fact discovery deadline is August 31, 2012; expert discovery closes October 31, 2012; and dispositive motions are due a week thereafter on November 7, 2012. (D.I. 142) The court is cognizant of the fact that Precision filed the motion at bar in August 2011; as the court takes up the motion, discovery nears a close. See *gen. Belden*, 2010 WL 3522327 at *2 (granting a request for stay later in the litigation is prejudicial to defendant given their investment in the case).

¹²See *Belden*, 2010 WL 3522327 at *3 (“[O]nly those reexamination proceedings that have been substantially completed will weigh in favor of a stay.”).

reasonable inference able to be drawn from the evidence.” *Id.* (quotation omitted).

As explained above, the alleged inequitable conduct in this case is Shier and Paques’ alleged mischaracterization of Arnould by Shier and Paques. (D.I. 113, ex. A at ¶¶ 22) It is not the case that Precision alleges that Collectis committed inequitable conduct by, for example, intentionally withholding material prior art from the PTO. The prior art allegedly mischaracterized – Arnould – was a focus of the prosecution. The examiner specifically sought the inventors’ comments on the reference.

Precision does not offer evidence of deceptive intent separate and apart from materiality, that is, Precision emphasizes that intent should be inferred from the inconsistency between Shier and Paques’ statements to the PTO during different prosecutions and the fact that a certificate of correction was filed. (D.I. 136 at 3-5 (“Dr. Shier and Dr. Paques must therefore have intentionally chosen to offer a different and inaccurate description of [Arnould] in order to secure allowance of the ‘372 patent’s claims”); D.I. 113, ex. A at ¶¶ 23, 28, 31) The court cannot rely solely on a finding of materiality to infer intent; both are separate requirements. *See Cancer Research Tech. Ltd. v. Barr Labs., Inc.*, 625 F.3d 724, 733 (Fed. Cir. 2010). That is, the court “must find some other evidence that indicates that the applicant appreciated the information’s materiality.” *Id.* (citation omitted) (holding that common authorship to a study containing contradictory data did not establish that the data was withheld with an intent to deceive).

The court appreciates Precision’s position that Shier and Paques expressly contradicted the teachings of Arnould. Precision does not cite authority demonstrating that this fact may substitute for independent evidence of intent to deceive, however, where the prior art at issue was a focus of the examination. Here, both examiners were

free to credit or discount Shier and Paques' characterizations of Arnould in view of their own readings. See *gen.* MPEP § 716.01(c) ("The arguments of counsel cannot take the place of evidence in the record."); *Akzo N.C. v. U.S. Intern. Trade Com'n*, 808 F.2d 1471, 1482 (Fed. Cir. 1986) (finding no inequitable conduct and stating that the "examiner was free to reach his own conclusion" as to validity in view of the prior art before him, notwithstanding counsel's arguments distinguishing that prior art).

Moreover, even assuming that Shier and Paques completely reversed their interpretation of Arnould prior to filing the July 26, 2010 preliminary amendment,

Precision

cannot drop the "atomic bomb" by mere conjecture that the prosecution attorney's zealous arguments were inequitable conduct. Attorneys prosecuting a patent should be able to correct mistakes, change their opinion, or adjust their argument to convince the examiner without risking invalidation of the patent by a later finding of inequitable conduct. As devastating as inequitable conduct can be, pleading the charge should require more.

Human Genome Sciences, Inc. v. Genentech, Inc., Civ. No. 11-6519, 2011 WL 7461786, *6-7 (C.D. Cal. Dec. 9, 2011) (citing *Therasense*, 649 F.3d at 1290). The PTO's granting of a certificate of correction to Collectis on its priority claim is not evidence of deceptive intent and, absent more, Precision's proposed inequitable conduct claim is deficient. Precision's motion to amend is denied on the basis of futility.

V. CONCLUSION

For the foregoing reasons, Precision's motions to stay and to amend its answer and counterclaims are denied. An appropriate order shall issue.